SUPPLEMENTARY MATERIALS

SUPPLEMENTAL METHODS

We selected two testing sites located in different geographic locations in order to reach a more diverse population and to increase the number of participants that we were able to enroll during the investigation period. A total of 3,463 nasal/NP swabs were collected for SARS-CoV-2 testing by BinaxNOW antigen and rRT-PCR. Of those, 11 were rejected for rRT-PCR testing, 3 participants ultimately declined antigen testing, 13 participants did not complete the REDCap survey, 14 had an inconclusive result (8 by rRT-PCR, 6 by BinaxNOW) and 3 were excluded from analysis due to being < 10 years of age. The 3,419 paired samples with complete testing and survey data were from 3,312 participants aged 10 or older. Ninety-seven participants participated twice and ten participated three times; sensitivity analysis showed no significant differences in BinaxNOW test performance when excluding multiple visits. Analysis presented here includes all 3,419 paired tests unless otherwise noted.

Swab Collection Procedure

The anterior nasal swab for BinaxNOW testing was collected using the swab provided in the kit per manufacturer's instructions for use [1]. The swab was carefully inserted by a trained health care professional into the nostril exhibiting the most visible drainage, or the nostril that was most congested if drainage not visible. Using gentle rotation, the swab was inserted into the first nostril until resistance was met at the level of the turbinate (less than one inch into the nostril), rotated 5 times or more against the nasal wall, and then slowly removed. The same swab was then used to repeat sample collection in the other nostril. The bilateral NP swab was collected following the swab for BinaxNOW testing and was collected according to the standard of care practice at the testing site and per CDC's guidelines for collecting and handling specimens [2].

BinaxNOW quality control, testing and results reporting

The Abbott BinaxNOW kits for this evaluation were provided by the Pima County Health Department (PCHD), who received them through the federal disbursement program. A commercial laboratory that routinely performed the rRT-PCR testing for the PCHD testing sites obtained a Clinical Laboratory Improvement Amendments waiver for the on-site BinaxNOW testing for this evaluation. The BinaxNOW kit lot numbers, manufacturer expiration dates, and kit storage conditions were documented on each patient test result sheet as part of the quality control management protocol developed for this evaluation. Per the BinaxNOW instructions for use, quality control testing of a positive and negative control from each new lot number of kits was conducted and results recorded. CDC staff who performed the on-site BinaxNOW testing were trained using a combination of reading material, including the site-specific standard operating procedure and BinaxNOW materials available online, the video demonstrations available on the Abbott website [3], and a hands-on in-person training session. Training competency was assessed by a short, written exam and by the correct performance of a positive and negative quality control test, which the trainer observed and documented.

After collection, AN swabs were immediately tested on-site by trained CDC staff using the BinaxNOW antigen test and read 15-30 minutes later according to manufacturer instructions for use [1]. Paper reporting forms with antigen test results were scanned into an electronic database and results discrepancies were resolved immediately. CDC and PCHD staff reported positive BinaxNOW results to participants by phone and counseled patients regarding home isolation and seeking medical care as needed. Results reporting by phone were documented in an Excel spreadsheet. Specimens with inconclusive or invalid results from either antigen or rRT-PCR testing were excluded from analyses.

SARS-CoV-2 viral isolation

Samples were cultured by limiting dilution in Vero CCL-81 cells and were observed daily for cytopathic effect in 96-well plates [4]. Wells that exhibited cytopathic effects were harvested, nucleic acid extracted, and presence of SARS-CoV-2 confirmed by rRT-PCR using the CDC 2019-nCoV rRT-PCR Diagnostic Panel for detection of SARS-CoV-2. A specimen was culture-positive if the first viral passage had an N1 Ct value at least two Ct values

lower than the clinical specimen. Twenty specimens with Ct values <18 had positive antigen and rRT-PCR results but were culture negative. The culture showed evidence of cytopathic effects and had presence of SARS-CoV-2 RNA as detected by rRT-PCR in the first passage culture, but viral recovery was not two Ct values lower than the corresponding clinical specimen Ct.

SUPPLEMENTAL RESULTS

BinaxNOW testing quality control

There were six invalid BinaxNOW test results identified. Four of the six were attributed to a manufacturing error. The other two invalid test results were due to reaction swab mixture not wicking up the test strip. Nine other test cards had manufacturing defects (e.g. test strip incorrectly aligned obscuring positive band window, absence of closure adhesive or plastic backing, misalignment of swab insertion hole), but defects were identified prior to initiating the test.

Reason for testing/Results reporting

Positive BinaxNOW results and counseling regarding isolation recommendations were given to patients by phone using Spanish-English bilingual staff. Based on discussions with PCHD and the testing site leads, this method was chosen for results reporting rather than electronic based reporting because many individuals in this population did not have equitable access to electronic devices or internet access for results reporting as well as overall ease of implementation for purposes of the evaluation. Furthermore, reporting results by phone using bilingual staff ensured equal access to communication around COVID-19 prevention strategies and for connecting patients to care. As shown in the main manuscript, 83% (134/161) of participants who tested positive by BinaxNOW and for whom times for results reporting were available, the average time from registration at the test site to reporting of BinaxNOW antigen test results was 2.5 hours compared to an average of 26 hours for rRT-PCR results reporting. Additionally, 4% (148) of rRT-PCR results were returned <24 hours (same day), 86% (2,940) were returned within 24 hours (next day), 10% (330) were returned within 48 hours and

0% (1) was returned after 96 hours. In this population, a significant portion of individuals sought testing (622/3419, 18.2%) because testing was required (e.g. for school or employment).

Supplemental Tables

Supplementary Table 1. Abbott BinaxNOW COVID-19 Antigen Test characteristics compared to rRT-PCR by gender, age, ethnicity, symptom and exposure status

	N (%)	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Male	**1,290 (100%)**	**52.9% (44.2-61.4)**	**99.9% (99.5-100)**	**98.6% (92.7-100)**	**94.7% (93.2-95.8)**
Currently Symptomatic	261 (20.2%)	66.7% (54.8-77.1)	100.0% (98.0-100)	100.0% (92.9-100)	88.2% (83.0-92.2)
Exposure	118 (45.2%)	69.8% (53.9-82.8)	100.0% (95.2-100)	100.0% (88.4-100)	85.2% (76.1-91.9)
No Exposure	143 (54.8%)	62.5% (43.7-78.9)	100.0% (96.7-100)	100.0% (83.2-100)	90.2% (83.6-94.9)
Previously Symptomatic	252 (19.5%)	40.5% (24.7-57.9)	100.0% (98.3-100)	100.0% (78.2-100)	90.7% (86.3-94.1)
Exposure	100 (39.7%)	37.5% (18.8-59.4)	100.0% (95.3-100)	100.0% (66.4-100)	83.5% (74.3-90.5)
No Exposure	152 (60.3%)	46.2% (19.2-74.9)	100.0% (97.4-100)	100.0% (54.1-100)	95.2% (90.4-98.0)
Never Symptomatic	777 (60.0%)	30.8% (14.3-51.8)	99.9% (99.3-100)	88.9% (51.2-99.7)	97.7% (96.3-98.6)
Exposure	234 (30.1%)	16.7% (0.4-64.1)	100.0% (98.4-100)	100.0% (2.5-100)	97.9% (95.1-99.3)
No Exposure	543 (69.9%)	35.0% (15.4-59.2)	99.8% (98.9-100)	87.5% (47.3-99.7)	97.6% (95.9-98.7)
Female	**1681 (100%)**	**57.5% (48.4-66.2)**	**99.8% (99.4-100)**	**96.1% (88.9-99.2)**	**96.6% (95.6-97.4)**
Currently Symptomatic	451 (26.9%)	66.7% (55.3-76.8)	100.0% (99.0-100)	100.0% (93.4-100)	93.2% (90.3-95.5)
Exposure	198 (43.9%)	70.6% (56.2-82.5)	100.0% (97.5-100)	100.0% (90.3-100)	90.7% (85.2-94.7)
No Exposure	253 (56.1%)	60.0% (40.6-77.3)	100.0% (98.4-100)	100.0% (81.5-100)	94.9% (91.2-97.3)
Previously Symptomatic	293 (17.4%)	28.0% (12.1-49.4)	99.6% (97.9-100)	87.5% (47.4-99.7)	93.7% (90.2-96.2)
Exposure	91 (31.0%)	22.2% (2.8-60.0)	100.0% (95.6-100)	100.0% (15.8-100)	92.1% (84.5-96.8)
No Exposure	202 (68.9%)	31.3% (11-58.7)	99.5% (97.0-100)	83.3% (35.9-99.6)	94.4% (90.2-97.2)
Never Symptomatic	937 (55.7%)	57.1% (34.0-78.0)	99.8% (99.2-100)	85.7% (57.2-98.2)	99.0% (98.2-99.6)
Exposure	250 (26.7%)	75.0% (34.9-96.8)	99.2% (97.x-100)	75.0% (34.9-96.8)	99.2% (97.x-99.9)
No Exposure	687 (73.3%)	46.2% (19.2-74.9)	100.0% (99.4-100)	100.0% (54.1-100)	99.0% (97.9-99.6)
Non-Hispanic/Latino	**1905 (100%)**	**50.9% (23.4-83.2)**	**99.8% (97.5-100)**	**95.2% (54.1-100)**	**96.9% (92.5-98.9)**
Currently Symptomatic	394 (20.4%)	66.7% (53.7-78.1)	100.0% (98.9-100)	100.0% (91.6-100)	94.0% (91.0-96.3)
Exposure	143 (36.3%)	69.4% (51.9-83.6)	100.0% (96.6-100)	100.0% (86.3-100)	90.7% (83.9-95.2)
No Exposure	251 (63.7%)	63.0% (12.4-24.8)	100.0% (98.4-100)	100.0% (80.5-100)	95.7% (92.3-97.9)
Previously Symptomatic	337 (17.5%)	33.3% (16.5-54.0)	99.7% (98.2-100)	90.0% (55.6-99.7)	94.5% (91.4-96.7)
Exposure	102 (30.3%)	29.4% (10.3-56.x)	100.0% (95.7-100)	100.0% (47.8-100)	87.6% (79.4-93.4)
No Exposure	235 (69.7%)	40.0% (12.2-73.8)	99.6% (97.5-100)	80.0% (28.4-99.5)	97.4% (94.4-99.0)

Never Symptomatic	1199 (62.1%)	32.1% (15.9-52.4)	99.8% (99.4-100)	81.2% (48.2-97.7)	98.4% (97.7-99.1)
Exposure	284 (23.7%)	44.4% (13.7-78.8)	99.6% (98.0-100)	80.0% (28.4-99.5)	98.2% (95.9-99.4)
No Exposure	915 (76.3%)	26.3% (9.1-51.2)	99.9% (99.4-100)	83.3% (35.9-99.6)	98.5% (97.4-99.2)
Hispanic/Latino	**1075 (100%)**	**56.7% (48.3-64.7)**	**99.9% (99.4-100)**	**98.8% (93.7-100)**	**93.4% (91.7-94.9)**
Currently Symptomatic	326 (30.3%)	66.3% (55.7-75.8)	100.0% (98.4-100)	100.0% (94.1-100)	88.3% (83.8-91.9)
Exposure	184 (56.4%)	64.4% (50.9-76.4)	100.0% (97.1-100)	100.0% (90.7-100)	85.6% (78.9-90.9)
No Exposure	142 (43.5%)	69.7% (51.3-84.4)	100.0% (98.7-100)	100.0% (85.2-100)	91.6% (85.1-95.9)
Previously Symptomatic	212 (19.7%)	35.1% (20.2-52.4)	100.0% (97.9-100)	100.0% (75.3-100)	87.9% (82.6-92.1)
Exposure	90 (42.4%)	38.9% (17.3-64.2)	100.0% (95.0-100)	100.0% (59.0-100)	86.7% (77.5-93.2)
No Exposure	122 (57.5%)	31.6% (12.6-56.5)	100.0% (96.5-100)	100.0% (54.1-100)	88.8% (81.6-93.9)
Never Symptomatic	537 (50.0%)	52.4% (31.0-73.3)	99.8% (98.9-100)	91.7% (61.5-99.9)	98.1% (96.5-99.1)
Exposure	214 (39.8%)	57.1% (18.4-90.1)	99.5% (97.3-100)	80.0% (28.4-99.5)	98.6% (95.9-99.7)
No Exposure	323 (60.1%)	50.0% (23.0-77.0)	100.0% (98.8-100)	100.0% (59.0-100)	97.8% (95.5-99.1)
Aged 10-17 years[a]	**236 (100%)**	**40.9% (20.7-63.7)**	**99.5% (97.4-100)**	**90.0% (55.5-99.8)**	**94.2% (90.4-96.9)**
Currently Symptomatic	49 (20.8%)	60.0% (26.2-87.8)	100.0% (90.1-100)	100.0% (54.1-100)	90.7% (77.9-97.4)
Previously Symptomatic	41 (17.4%)	33.3% (4.3-77.7)	100.0% (90.0-100)	100.0% (15.8-100)	89.7% (75.8-97.1)
Never Symptomatic	146 (62.9%)	16.7% (4.2-64.1)	99.3% (96.1-100)	50.0% (1.3-98.7)	96.5% (92.1-98.9)
Exposed	99 (42.0%)	53.8% (25.1-80.1)	98.8% (93.7-100)	87.5% (47.3-100)	93.4% (86.2-97.5)
Not Exposed	137 (58.0 %)	22.2% (2.8-60.0)	100.0% (97.1-100)	100.0% (15.8-100)	94.8% (89.6-97.9)
Aged 18-49 years	**1885 (100%)**	**50.0% (42.4-57.6)**	**99.9% (99.6-100)**	**97.8% (92.3-99.7)**	**95.0% (93.9-96.x)**
Currently Symptomatic	500 (26.5%)	61.8% (52.1-70.9)	100.0% (99.1-100)	100.0% (94.7-100)	90.3% (87.1-92.9)
Previously Symptomatic	395 (20.9%)	31.1% (18.2-46.7)	99.7% (98.4-100)	93.3% (68.1-99.8)	91.8% (88.6-94.4)
Never Symptomatic	990 (52.2%)	30.4% (13.2-53.0)	99.9% (99.4-100)	87.5% (47.4-99.7)	98.4% (97.4-99.1)
Exposed	702 (37.2%)	52.0% (41.8-62.0)	100.0% (99.4-100)	100.0% (93.3-100)	92.4% (90.1-94.4)
Not Exposed	1183 (62.8%)	47.4% (35.8-59.2)	99.8% (99.4-100)	94.7% (88.3-99.4)	96.5% (95.3-97.5)
Aged 50-64 years	**743 (100%)**	**58.0% (45.5-69.8)**	**99.9% (99.2-100)**	**97.6% (87.1-99.9)**	**95.9% (94.1-97.2)**
Currently Symptomatic	179 (24%)	70.0% (53.5-83.4)	100.0% (97.4-100)	100.0% (87.7-100)	92.1% (86.5-95.8)
Previously Symptomatic	115 (15.5%)	35.7% (12.8-64.9)	100.0% (96.4-100)	100.0% (47.8-100)	91.8% (85.0-96.2)
Never Symptomatic	449 (60.4%)	46.6% (21.3-73.4)	99.8% (98.7-100)	87.5% (47.4-99.7)	98.2% (96.5-99.2)
Exposed	218 (29.3%)	64.3% (44.1-81.4)	99.5% (97.1-100)	94.7% (74.0-100)	93.4% (86.2-97.5)
Not Exposed	525 (70.7%)	53.7% (37.4-69.3)	100.0% (99.2-100)	100.0% (84.6-100)	94.8% (89.6-97.9)
Aged ≥ 65 years	**555 (100%)**	**63.3% (43.9-80.1)**	**100.0% (99.3-100)**	**100.0% (82.4-100)**	**97.9% (96.4-99.0)**
Currently Symptomatic	99 (17.8%)	68.8% (41.3-89.0)	100.0% (95.7-100)	100.0% (71.5-100)	94.3% (87.2-98.1)

Previously Symptomatic	73 (13.3%)	40% (5.3-85.3)	100.0% (94.7-100)	100.0% (15.8-100)	95.8% (88.1-99.1)
Never Symptomatic	383 (69.0%)	66.7% (30.0-92.5)	100.0% (99.0-100)	100.0% (54.1-100)	99.2% (97.7-99.8)
Exposed	119 (21.4%)	68.4% (43.4-87.4)	100.0% (96.3-100)	100.0% (75.3-100)	94.3% (88.0-97.9)
Not Exposed	436 (18.6%)	54.6% (23.4-83.2)	100.0% (99.1-100)	100.0% (54.1-100)	98.8% (97.3-99.6)

[a] Sample size insufficient for all age groups to allow further subdivision by symptom/exposure status.

Supplementary Table 2. Culture positivity and Abbott BinaxNOW COVID-19 Antigen Test / rRT-PCR test results by symptom and exposure status

Symptomatic[b] and Exposure[c] Group	Culture Positive/Total[a] (%)		
	Overall	Ag+/rRT-PCR+ specimens (concordant positive)	Ag-/rRT-PCR+ specimens (false negative)
All Specimens[d]	35.4% (96/271)	57.8% (85/147)	8.9% (11/124)
Symptomatic	41.7% (68/163)	59.4% (63/106)	8.8% (5/57)
Exposure	40.0% (40/100)	56.1% (37/66)	8.8% (3/34)
No Exposure	44.4% (28/63)	65.0% (26/40)	8.7% (2/23)
Previously Symptomatic	25.0% (16/64)	59.1% (13/22)	7.1% (3/42)
Exposure	18.2% (6/33)	45.5% (5/11)	4.6% (1/22)
No Exposure	32.3% (10/31)	72.7% (8/11)	10.0% (2/20)
Never Symptomatic	27.3% (12/44)	47.4% (9/19)	12.0% (3/25)
Exposure	42.9% (6/14)	71.4% (5/7)	14.3% (1/7)
No Exposure	20.0% (6/30)	33.3% (4/12)	11.1% (2/18)

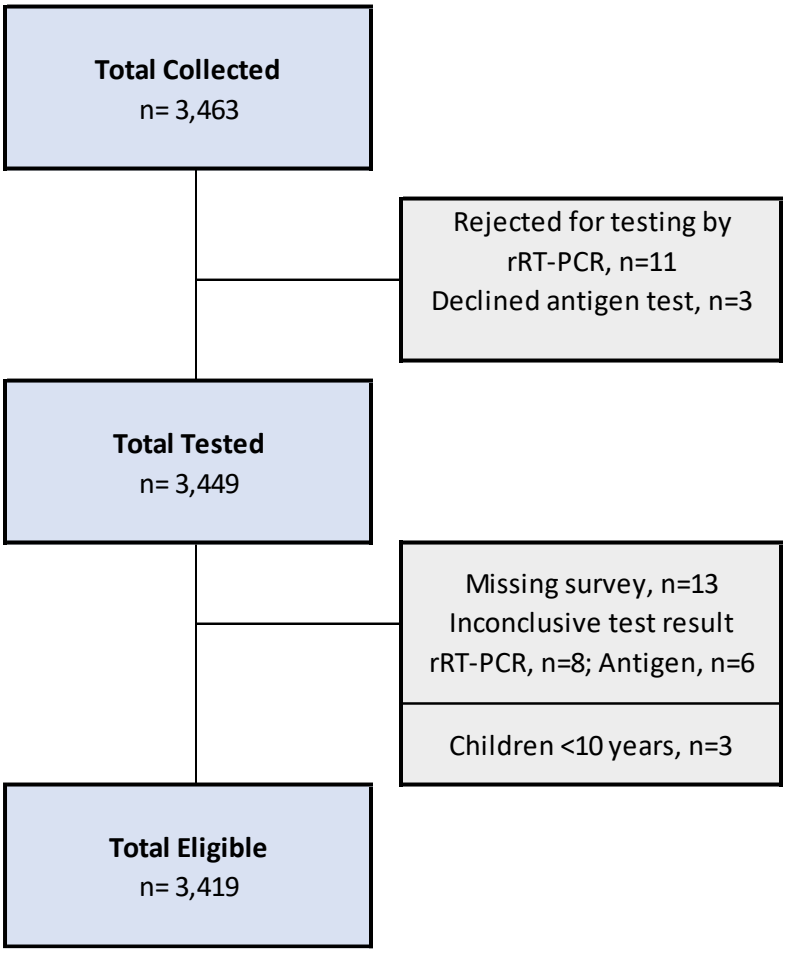
[a]Denominator includes the total number of residual rRT-PCR positive specimens that were analyzed by viral culture.

[b]Participants were asked if they had symptoms in 14 days prior to testing and/or at time of testing, here we classified currently symptomatic as ≥ 1 symptom at time of test. Those classified as previously symptomatic reported symptoms in the 14 days prior to but not on day of test. Those classified as never symptomatic reported no symptoms in the 14 days prior to or on day of test.

[c]Reported close contact (within 6ft for ≥15 minutes) in the 14 days prior to day of testing with a person diagnosed with COVID-19.

[d]Previously reported data from brief report[5]

Supplementary Figure 1



Supplementary Figure 1. Total paired swabs collected, tested and eligible for inclusion (showing reasons for exclusion) during an evaluation of the Abbott BinaxNOW COVID-19 Ag Card Point of Care Diagnostic Test at two community-based testing sites – Pima County, Arizona, November 2020

Blue boxes show the total paired swabs collected, tested and ultimately eligible for inclusion in analysis. Gray boxes show participants excluded, by reason for exclusion.

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